and would exempt them from the premarket notification (510(k)) and current good manufacturing practice (CGMP) requirements. The proposal would also restrict these devices under section 520(e) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360j(e)) to require the following: (1) The laboratory test(s) incorporated into these systems would be required to have been cleared, approved, or otherwise recognized by FDA as accurate and reliable for laboratory use; (2) the laboratory performing the underlying test(s) must be able to reliably perform the necessary screening and confirmatory tests; and (3) the samples must be adequately identified to avoid mix-ups and the test sample collection system must be accurately labeled so that consumers can readily use it. The draft guidance will help manufacturers meet this third criterion if the regulation becomes final and also can be used by manufacturers currently marketing these products under FDA's Interim Policy regarding ''Parents' Access to Tests for Drugs of Abuse.'' This draft guidance also addresses the need to provide consumers with access to professional assistance in interpreting/understanding test results and counseling referrals.

II. Significance of Guidance

This draft guidance document represents the agency's current thinking on labeling of over-the-counter sample collection systems for drugs of abuse testing. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the applicable statute, regulations, or both.

The agency has adopted good guidance practices (GGP's), which set forth the agency's policies and procedures for the development, issuance, and use of guidance documents (62 FR 8961, February 27, 1997). This guidance document is issued as a Level 1 guidance consistent with GGP's.

III. Electronic Access

In order to receive the draft guidance entitled ''Guidance on Labeling for Over-the-Counter Sample Collection Systems for Drugs of Abuse Testing'' via your fax machine; call the CDRH Facts-On-Demand (FOD) system at 800–899–0381 or 301–827–0111 from a touch-tone telephone. At the first voice prompt press 1 to access DSMA Facts, at second voice prompt press 2, and then enter the document number (1154) followed by the pound sign (#). Then follow the remaining voice prompts to complete your request.

Persons interested in obtaining a copy of the draft guidance may also do so using the Internet. CDRH maintains an entry on the Internet for easy access to information including text, graphics, and files that may be downloaded to a personal computer. Updated on a regular basis, the CDRH home page includes the draft guidance entitled ''Guidance on Labeling for Over-the-Counter Sample Collection Systems for Drugs of Abuse Testing,'' device safety alerts, **Federal Register** reprints, information on premarket submissions (including lists of approved applications and manufacturers' addresses), small manufacturers' assistance, information on video conferencing and electronic submissions, mammography matters, and other device-oriented information. The CDRH home page may be accessed at http://www.fda.gov/cdrh. ''Guidance on Labeling for Over-the-Counter Sample Collection Systems for Drugs of Abuse Testing'' will be available at http://www.fda.gov/cdrh/ggpmain.html#docs.

IV. Paperwork Reduction Act of 1995

The information collection provisions referred to in this guidance have been approved under OMB control number 0910–0368. This approval expires April 30, 2001. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

V. Comments

Interested persons may, on or before March 22, 2000, submit to Dockets Management Branch (address above) written comments regarding this draft guidance. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The guidance document and received comments may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: December 10, 1999.

Linda S. Kahan,

Deputy Director for Regulations Policy, Center for Devices and Radiological Health.

[FR Doc. 99–33002 Filed 12–20–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Notice of Establishment

Pursuant to the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), the Director, National Institutes of Health (NIH), announces the establishment of the PubMed Central National Committee (Committee).

This Committee will advise the Director, NIH, the Director, National Library of Medicine, and the Director, National Center for Biotechnology Information, on the content and operation of the PubMed Central repository. The Committee will establish criteria to certify groups submitting materials to the system, monitoring the operation of the system, and ensuring that PubMed Central evolves and remains responsive to the needs of researchers, publishers, librarians and the general public.

Unless renewed by appropriate action prior to its expiration, the charter for the PubMed Central National Advisory Committee will expire two years from the date of establishment.

Dated: December 15, 1999.

Harold Varmus,

Director, National Institutes of Health.

[FR Doc. 99–32966 Filed 12–20–99; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Center for Research Resources; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Center for Research Resources Special Emphasis Panel Biomedical Research Technology.

Date: January 5, 2000.